Status of the Claims:

Claims 1-20 and 22-37 are pending in the application.

Claim 21 was cancelled without prejudice or disclaimer.

Claims 1, 9, 16-20, 22-24, 31 and 37 stand rejected.

Claims 2-8, 10-15, 25-30, and 32-36 are objected to as being dependent from the rejected claims.

Remarks

The Final Office Action dated April 9, 2003 has been carefully reviewed and the foregoing amendments are made in response thereto. Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Summary of the Office Action

1. The drawings are objected to by the Draftsperson.
2. The specification was objected to for missing the priority statement.
3. The rejection of claims 1-8 and 16-17 under 35 U.S.C. 102(b) as being anticipated by McDonald *et al.* was withdrawn.
4. The rejection of claims 9-15 and 18-19 under 35 U.S.C. 103(a) as being unpatentable over McDonald *et al.* in view of Riggs *et al.* was withdrawn.
5. The rejection of claims 20, 22-23 under 35 U.S.C. 112 (first paragraph) was maintained pending allowance of the claims and perfection of the deposit requirement.
6. Claim 24 was objected to under 37 C.F.R. 1.75 as being a substantial duplicate of claim 1.
7. Claims 1, 9, 24, 31 and 37 were rejected under 35 U.S.C. 112 (first paragraph) as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention.
8. Claim 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald *et al.*

Drawings

Applicants will submit substitute drawings upon finding of allowable subject matter and request that the Examiner hold this objection in abeyance until such time.

Priority Statement

The specification has been amended to include a priority statement. Applicants respectfully request that the application be amended so that the priority information is correct on the face of any patent to issue from this application.

Rejections under 35 U.S.C. 112

The Office Action rejected claims 20, 22-23 under 35 U.S.C. 112 (first paragraph) for failing to provide an enabling disclosure because the specification lacks complete deposit information for the clone CRY 104. Applicants submit herewith a copy of the receipt for the ATCC deposit for the clone CRY 104.

The Office Action rejected claims 1, 9, 24, 31 and 37 under 35 U.S.C. 112 (first paragraph) as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention.

The basis of this rejection is that the newly added limitation "free from sporozoite antigens" has no antecedent in the descriptive portion of the original disclosure. The Examiner's attention is respectfully drawn to the disclosure at page 4, lines 1-7 which states:

> The present inventors have found that in order to obtain suitable oocyte wall antigen preparation, the oocyst wall should be separated from internal sporozoite components. It appears that the internal sporozoite antigens are more immunodominant than oocyst wall antigens and their [internal sporozoite antigens] presence in an antigen preparation may mask the oocyst wall antigens. A mixed antigen preparation will usually result in raising antibodies to the sporozoite antigens.

It is respectfully submitted that it would be clear to a person skilled in the relevant art that this passage teaches that the oocyte antigen preparation should be free from sporozoite antigens and thereby provides support for the recitation of the preparation being free from sporozoite antigens.

Objection under 37 C.F.R. 1.75

The Office Action has objected to claim 24 under 37 C.F.R. 1.75 as being a substantial duplicate of claim 1.

The language of step (a) in claim 1 requires the pretreatment of *Cryptosporidium* oocysts with a reagent so as to remove the surface layer of the oocyst to form an oocyst antigen preparation. The corresponding step in claim 24 requires the pretreatment of *Cryptosporidium* oocysts with a reagent that removes surface layer antigens to form an oocyst surface antigen preparation. It is respectfully submitted that claims 1 and 24 are not duplicates in that claim 1 step (a) recites removal of the surface layer (which contains the antigens) whereas claim 24 recites removal of surface antigens, which does not necessarily require removal of the surface layer. It is respectfully submitted that this difference is not a mere difference in wording.

Rejection under 35 U.S.C. 102(b)

Claims 16-19 have been rejected under 35 U.S.C. 102(b) for allegedly being anticipated by McDonald *et al.* (1995).

The Examiner views these claims as defining a product by process. In addition, the Examiner alleges that the products of the prior art reference appear to be the same, or an obvious or analogous variant of the product presently claimed by the applicant because they appear to possess the same or similar functional characteristics. The Examiner alleges that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art.

Applicants respectfully disagree with the Examiner's analysis insofar as it is asserted that the product of the present process is the same as the product taught by McDonald *et al.* As noted in the amendment dated 6 May 2002, McDonald *et al.* effectively discloses antibodies against oocyst antigens that were produced by the earlier method disclosed in McDonald *et al.* (1991). This earlier reference discloses a method whereby intact oocysts are homogenised and subsequently injected into Balb/c mice for the generation of monoclonal antibodies. As each intact oocyst contains a sporozoite, the homogenate used in McDonald *et al.* (1991) contained sporozoite antigens, resulting in the formation of antibodies against sporozoites. This is in contrast to the product of the method of present claim 1 where, because the IgG1 antibodies are elicited by use of oocyte antigens free of sporozoite antigens, the final product will not contain antibodies to sporozoite antigens. As discussed above, it appears that the internal sporozoite

antigens are more immunodominant that oocyst antigens and the presence of the sporozoite antigens may mask the oocyst wall antigens. Therefore, it is respectfully submitted that the product of McDonald *et al.* is not the same product of claims 16-19. The product of McDonald *et al.* would have contained antibodies against sporozoite antigen, which is absent from the present product. This is not merely a difference in purity.

The Examiner further argues that even if the present product is of a higher purity than that in the cited reference, Applicants' product would have been *prima facie* obvious over the product of the cited reference since one of ordinary skill in the art, being motivated by the expectation of success and the attainment of greater specific activity with increased purity, could have used conventional techniques in the product field to further purify and characterize the product. If the Examiner is suggesting that "purification" includes removal of sporozoite antibodies, we respectfully submit that the Examiner is using hindsight analysis as there would appear to be no motivation in the cited reference to avoid the production of antibodies to sporozoites or to remove them from the final product by purification.

Conclusion

In view of the foregoing, Applicants respectfully request reconsideration and the timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for in the attached petition, such an extension is requested and the fee should also be charged to our Deposit Account No. 50-0310.

Respectfully submitted
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Registration No. 50,801

Dated: **January 9, 2004**
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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Biotech Frontiers
Attn: Graham Vesey
P.O. Box 599
North Ryde BC NSW
Australia

Deposited on Behalf of: Macquarie Research Limited

Identification Reference by Depositor:	**Patent Deposit Designation**
Hybridoma Cell Line: CRY104	PTA-4250

The deposit was accompanied by: __ a scientific description _ a proposed taxonomic description indicated above.

The deposit was received April 25, 2002 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested May 1, 2002. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris

Marie Harris, Patent Specialist, ATCC Patent Depository

Date: May 21, 2002

cc: Nick Finnie
(Ref: Docket or Case No.: 87609/NJF)